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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/649,837 | 08/28/2003 | Marius Hauri | 0100/0149 | 6648 |
| 21395 | 7590 | 05/04/2006 | EXAMINER | |
| LOUIS WOO LAW OFFICE OF LOUIS WOO 717 NORTH FAYETTE STREET ALEXANDRIA, VA 22314 | | | | WITCZAK, CATHERINE |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3767 | |

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/649,837 | HAURI, MARIUS | |
| | Examiner | Art Unit | |
| | Catherine N. Witczak | 3767 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 April 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 11-13 is/are allowed.
- 6) Claim(s) 1-4, 6, 10, 14-17 and 23-27 is/are rejected.
- 7) Claim(s) 5, 18-22 and 28 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

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## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 6, 7, 8, 14, 15, 16, 23, 25, and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Kobayashi et al (US 6,719,737).

*Claim 1:* Kobayashi et al disclose in Figure 1 a needle hub (20) having a needle (40), a collar (50) rotateably mounted about needle hub, and a needle sheath (70) removably attached to the collar.

*Claim 2:* Kobayashi et al disclose in Figure 1 a housing (80) connected to the collar (50) that is pivotable to a position substantially in alignment along a longitudinal axis.

*Claim 4:* Kobayashi et al disclose in Figure 15 needle sheath (70) comprising a spline that fits into a hub slot (spaces between 28), wherein the hub is rotatable with rotation of the sheath (column 11, lines 51-61).

*Claim 6 and 14:* Kobayashi et al disclose in Figure 2 a hub comprising a distal and proximal end, the distal portion comprising arms (28) which form slots for coaction with the sheath spline (column 11, lines 51-61), and flanges (30) extending from the proximal portion.

*Claim 7:* Kobayashi et al disclose in Figure 2 a hub with a luer end on the proximal part (39), and a proximal neck from which the needle (26) extends.

*Claim 8:* Kobayashi et al disclose in Figure 5 a collar with at least one protrusion (58) on its interior surface and one finger (69) to engage with the sheath.

*[Handwritten signature]*

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*Claim 15:* Kobayashi et al disclose in Figure 2 hub flanges that are beveled for fitting the collar onto and the collar being rotateable about the space (column 5, lines 60-64).

*Claim 16:* Kobayashi et al disclose in Figure 2 the hub having a luer end (39) for mating with a syringe.

*Claim 23:* Kobayashi et al disclose in Figure 1 a hub (20), a needle (40), a rotatably mounted collar (50), and a needle sheath (70).

*Claim 25:* Kobayashi et al disclose in Figure 2 a hub comprising a distal and proximal end, the distal portion comprising arms (28) which form slots for coaction with the sheath spline (column 11, lines 51-61), and flanges (30) extending from the proximal portion, and flanges that are beveled for fitting the collar onto.

*Claim 26:* Kobayashi et al disclose in Figure 3 a collar with protrusions (58) on its interior surface that fit the flanges on the hub in order to connect the collar rotatably to the hub and one finger (69) to engage with the sheath.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kobayashi et al in view of Gyure et al (5,665,075).

Kobayashi et al disclose the claimed invention except for the housing having at least one internal spline coactable with at least one catch on the hub to facilitate separation the hub. Gyure et al disclose in column 9, lines 26-37 the housing having internal splines coactable with a catch on the hub to facilitate

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separating the hub from the syringe. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Kobayashi with a housing having internal splines coactable with a catch on the hub as taught by Gyure et al to facilitate separating the hub from the syringe.

2. Claims 17 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobayashi et al as modified by Landis (US 5,490,841).

Gyure et al disclose the claimed invention except for the housing having an off centered opening formed by two lips, with the first lip overlapping the second lip. Landis teaches that it is known to use a housing having an off centered opening formed by two lips (20 and 26), with the first lip (26) overlapping the second lip (20) in Figure 2 to prevent the needle from exiting the housing in the case the housing is rotated with respect to the base as set forth in column 2, lines 31-35. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Gyure et al with a housing having an off centered opening formed by two lips, with the first lip overlapping the second lip as taught by Landis, since such a modification would provide the system with a way to prevent the needle from exiting the housing in the case the housing were rotated with respect to the base. [Claims 17 and 24]

3. Claims 9, 10, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobayashi et al as modified by Hollister (6,328,713).

Kobayashi et al disclose the claimed invention except for the collar having a lock mechanism that interacts with a housing lock, wherein the collar lock is a catch member and the housing lock is an aperture. Hollister teaches in Figure 5 a collar (2) having a lock mechanism (38) which interacts with a housing lock (36) wherein the collar locks are catch members and the housing locks are apertures to prevent the housing from moving relative to the collar once the housing is used to cover the needle

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(column 2, lines 1-5). It would have been obvious to once having ordinary skill in the art at the time the invention was made to modify the system as taught by Kobayashi et al with a collar having a lock mechanism that interacts with the housing locks, wherein the collar locks are catch members and the housing locks are apertures, as taught by Hollister, since such a modification would prevent the housing from moving relative to the collar once the housing is used to cover the needle.

***Allowable Subject Matter***

2. Claims 11-13 are allowed. The following is a statement of reasons for the indication of allowable subject matter: the independent claim discloses a housing having a longitudinal opening formed by first and second lips each extending substantially along the length of the housing, with the first lip overlapping a portion of the second lip with the opening being off centered, each of the lips being angled towards the interior of the housing with the respective angles of each of the lips being varied along the length of the housing. Prior art teachings disclose a housing having a longitudinal opening formed by first and lip overlapping a portion of the second lip with the opening being off centered, however no prior art teaches, discloses, or fairly suggests the lips being angled towards the interior o the housing with the respective angle of each of the lips being varied along the length of the housing.

5. Claims 5, 18-22, and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Withdrawn Objections***

Objection to the abstract made in previous action is withdrawn in response to Applicants submission of corrected abstract.

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***Response to Arguments***

Applicant's arguments with respect to claim1-28 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine N. Witczak whose telephone number is (571) 272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KEVIN SIRMONS  
PRIMARY EXAMINER

cw

WWWWWW

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*Kevin C. Sirmons*